

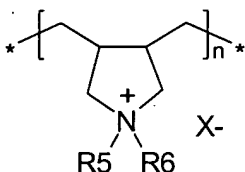
wherein R5 = H, or an alkyl chain from C₁ to C₂₂,

R6 = H, or an alkyl chain from C₁ to C₂₂, and

X = a pharmaceutically acceptable anion.

84. (New) A polymer, salt or copolymer thereof, characterized by a repeat unit having the formula:

(X)



wherein R5 = H, R6 = CH₃ and X = tartrate.

REMARKS

Claim Amendments and Petition of Restriction Requirement

Claims 49-55 and 76 were mistakenly cancelled in the Amendment filed November 19, 2002. Applicants regret the error and any confusion resulting therefrom. New Claims 77-84 are essentially identical to cancelled Claims 49-55 and 76; grammatical errors have been corrected.

Applicants are filing a Petition Under C.F.R. § 1.144 to request review of the Examiner's decision to maintain the Restriction Requirement. The claims of Group VI, as set forth in the Restriction Requirement, are now embodied by new Claims 77-84.

Rejection of Claims 71 and 73 Under 35 U.S.C. § 103(a)

Claims 71 and 73 are rejected under 35 U.S.C. § 103(a) as being obvious over Niike, *et al.* (JP H04-333694). The Examiner stated that Niike, *et al.* disclose a copolymer of a methacrylate ester and an ammonium bearing monomer, where the monomer is a substituted diallylammonium and the copolymer is part of an emulsion composition. The Examiner stated that the substituents for the diallylammonium include methyl, ethyl, propyl, hydroxyethyl, hydroxypropyl and dihydroxypropyl (although the Examiner subsequently stated that dihydroxypropyl is not disclosed). The Examiner further stated that water is present in the emulsion, and the Examiner asserts that the water is an inert pharmaceutical adjuvant material.

Applicants have obtained an imprecise translation of the Niike, *et al.* reference using the mechanical translation tool available through the Japan Patent Office's website. A copy of the translation is enclosed as "Exhibit A." Applicants request that the Examiner provide a full translation of passages cited from Niike, *et al.* in any future Office Actions. Niike, *et al.* is directed to an emulsification dispersant for rosin system emulsion sizing compounds, which are used in paper manufacture. Although water can be a component of the emulsion, there is no teaching or suggestion in Niike, *et al.* that this water is sterile water or water of a sufficient purity to be safe for pharmaceutical use. **Based on the teachings of Niike, *et al.*, it is unreasonable to assume that the water in the emulsion constitutes an inert pharmaceutical adjuvant.**

Instead, it is probable that the water is not inert, because impurities in the water would have an active, toxic effect on a subject being treated. Moreover, it does not appear that any other substance disclosed by Niike, *et al.* is suitable for use in a pharmaceutical composition.

Because Niike, *et al.* does not teach that the water, which is disclosed to be a component of a polymer-containing emulsion, is suitable for use in pharmaceutical compositions, the reference does not teach or in any way suggest a pharmaceutical composition comprising polymers having the structures shown in Claims 71 and 73 and an inert pharmaceutical adjuvant material. Thus, Claims 71 and 73 are not obvious in view of Niike, *et al.* Reconsideration and withdrawal of the rejection are requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

Respectfully submitted,

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